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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.           | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------------|------------------|
| 10/074,687   | 02/11/2002  | Feng-Jing Chen       | 6200-0004.20                  | 9747             |
| 20551  | 7590        | 07/22/2005           | EXAMINER                      |                  |
| THORPE NORTH & WESTERN, LLP.<br>8180 SOUTH 700 EAST, SUITE 200<br>P.O. BOX 1219<br>SANDY, UT 84070 |             |                      | CHANNAVAJJALA, LAKSHMI SARADA |                  |
|  |             |                      | ART UNIT                      | PAPER NUMBER     |
|  |             |                      | 1615                          |                  |

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/074,687

Applicant(s)

CHEN ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-145 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 18-23, 38, 67-71, 88-93, 108 and 134-145 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-17, 24-37, 39-66, 72-87, 94-107 and 109-133 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt of remarks dated 5-16-05 is acknowledged.

Claims 1-145 are present. Claims 1, 2, 5-17, 24-37, 39-66, 72-87, 94-107 and 109-133 have been examined. Claims 3, 4, 18-23, 38, 67-71, 88-93, 108 and 134-145 are withdrawn as being non-elected.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1, 2, 5-17, 24-37, 39-66, 72-87, 94-107 and 109-133 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 103***

Claims 1, 2, 5-17, 24-37, 39-66, 72-87, 94-107 and 109-133 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,922,355 to Parikh et al (Parikh).

Parikh teaches composition and method of preparing microparticles of water-insoluble microparticles, using combination of one or more surface modifiers/surfactants such as poloxamers, poloxamines, polyoxyethylene sorbitan fatty acid esters and phospholipids. Parikh teaches that the compositions comprising the particles resist the growth of the particle size because of the presence of surfactants such as that are adsorbed to the surface of the particles and also maintain the micron and sub-micron particle sizes even after storage as a suspension or as a solid dosage form (col. 2, lines 24-34 ). Parikh teaches using water-insoluble or poorly soluble drugs belong to various classes such as immunomodulator, antihypertensive agents, anti-fungal, hormones, and other suitable drugs having the above solubility, in the instant composition (col. 2, lines

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44-64). In addition to the surfactants such as phospholipids, Parikh teaches second surface modifiers (col. 3, lines 5-32), with particular reference to poloxamers, poloxamines, pluronic etc., which are described in the instant application. Parikh teaches the second surfactants for maintaining the desired particle size, storage stability and minimization of sedimentation etc (col. 3, lines 50-66). With respect to the process of preparing the composition, Parikh teaches that the drug substance is mixed with phospholipid, second surfactants and other pharmaceutical additives before reducing the particle size to the desired size (claim 1 and examples).

Parikh fails to specifically teach the claimed first fraction and second, percentages of the fractions. Parikh also fails to teach the absence of water, of the instant claims. However, Parikh suggests employing drugs that are poorly soluble, in particular with the solubilities of less than 5 mg/ml. Thus, depending on the solubility of the drug selected, a poorly soluble drug does remain solubilized to some extent (in the composition of Parikh), while a majority portion remains suspended. Further, Parikh teaches various concentrations of surfactants so as to maintain the particles size, proportion etc. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to prepare a pharmaceutical composition wherein the active agent is present as both particles as well as in a solubilized form by optimizing the amount of the surfactant because Parikh suggests that the amount of particle sedimentation, particle size etc., can be optimized by the amount of surfactant adsorbed on the surface of the particles. Therefore, depending on the drug used, a skilled artisan would have been able to optimize the particulate or solubilized amount of

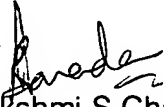
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drug and accordingly the release rates achieved. Further, Parikh teaches both solid and liquid dosage forms and accordingly, adding water or not, or adjusting the amounts of water in the composition of Parikh depending on the final form of the composition would have been within the scope of a skilled artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Lakshmi S Channavajjala  
Examiner  
Art Unit 1615

July 14, 2005